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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/076,115	05/12/1998	CHRISTIAN E. GRUBER	0942.4350001	4470

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/18/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/076,115

Applicant(s)
Gruber et al

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 30, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32, and 54-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32, and 54-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2002 has been entered.
2. Applicant's arguments with respect to the rejection of claims 1-2, 6, 12, 16-20, 22, 25, 28-29, 31-32, and 54-56 under 35 U.S.C. §102(e) as being anticipated by Burmer (5,726,022) and under 35 U.S.C. §103(a) over Frohman (PCR protocols, a guide to methods and applications, 1990, pg. 28-38) in view of Lohman et al. (5,631,147) have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 55 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 55 is vague and indefinite because of the language “ at least one of said nucleic acid templates is polyadenylated”. Since RNA molecule has a poly A region, it is unclear whether or not the polyA region is naturally there or is added as claimed. Clarification is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2, 6, 12, 16-20, 22, 25, 28-29, 31-32, 54, and 56-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (5,726,022).

Burmer discloses that an adaptor with a restriction site is ligated to a first nucleic acid sample and optionally the adaptor may contain a ligand binding end. Further, Burmer discloses that if the first and second nucleic acid fragment are amplified, they are amplified with primers containing a ligand binding end and a sequence complementary to the adaptors (See column 2, lines 39-48).

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Burmer does not disclose using a primer-adapter nucleic acid. However, the primer of Burmer containing a ligand binding end and a sequence complementary to the adaptors (See column 2, lines 45-48). One of ordinary skill in the art would have made the primer-adapter nucleic acid because of the teachings of Burmer in that the primer of Burmer contains a sequence complementary to the adaptors (See column 2, lines 45-48).

Burmer discloses that amplification may be done by PCR, LCR or TAS (see column 8, lines 47-52) (as recited in claims 12, 16,). This indicates that the polypeptides as listed in claim 6 are involved in the method of the invention, for example, reverse transcriptase and *Taq* DNA polymerase. The isolation step is done by first removing the adaptors by restriction enzyme, capturing the nucleic acid containing the ligand and then the nucleic acid that were not captured is isolated (see column 2, lines 56-59) (as recited in claims 20 and 31-32). The ligand includes hapten (see column 7, line 4) (as recited in claims 18-19). The solid support is described in column 7, lines 37-48 (as recited in claims 22).

Burmer does not disclose the template is an RNA molecule as amended and as argued in the response filed 10/30/2002. However, DNA and RNA molecule has similar structure, which was well known in the art at the time of the instant invention. The method for amplifying DNA can be applied to amplify RNA molecule. Therefore, one of ordinary skill in the art would have been motivated to apply the method of Burmer to make a nucleic acid molecule from an RNA molecule or mRNA molecule. Thus, it would have been prima facie obvious to carry out the method as claimed.

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7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

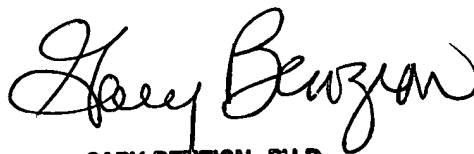
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

December 15, 2002



GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600